

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

ANTRIM PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	No. 16-cv-00784
BIO-PHARM, INC.,	)	
	)	
Defendant.	)	
	)	
	)	

**COMPLAINT**

Plaintiff, Antrim Pharmaceuticals LLC, by and through its attorneys, Winston & Strawn LLP, for its Complaint against Bio-Pharm, Inc. states:

**Nature of Action**

1. This is an action for breach of contract resulting from Defendant Bio-Pharm, Inc.’s (“Bio-Pharm”) failure to fulfill its obligations to manufacture and deliver Escitalopram Oral Solution pursuant to its agreement with Plaintiff Antrim Pharmaceuticals LLC (“Antrim”).

2. After years of time, effort and expense, Antrim obtained approval of the United States Food and Drug Administration (“FDA”) to produce and market Escitalopram Oral Solution (the “Product” — brand name “LEXAPRO”) under its own, government approved, Abbreviated New Drug Application (“ANDA”).

3. Antrim relied on its agreement with Bio-Pharm and obtained this FDA approval using Product manufactured by Bio-Pharm made pursuant to Antrim’s formulation. Bio-Pharm had not previously manufactured the Product and relied on Antrim’s formulation to produce the Product.

4. Under the terms of the parties' agreement, Bio-Pharm was obligated to manufacture the Product exclusively for Antrim and deliver the Product to Antrim in exchange for 20% of net profits and reimbursement of its out-of pocket costs.

5. Now that FDA approval has been obtained for Antrim's product, Bio-Pharm has wrongfully retained the Product it has manufactured to date and refused to manufacture additional Product unless paid additional compensation together with an "equity" interest in the Product. In essence, Bio-Pharm is wrongfully holding the Product hostage to its demand for money.

6. As a result of Defendant's breach, Antrim has suffered lost sales, lost profits and consequential damages of not less than \$5 million.

### **Parties**

7. Antrim, an Illinois limited liability company (whose members are citizens of Illinois and Arizona), is a generic drug manufacturer with its principal place of business in Lake Forest, Illinois.

8. Bio-Pharm, a Pennsylvania corporation, is a contract manufacturer of generic pharmaceutical products with its principal place of business in Levittown, Pennsylvania.

### **Jurisdiction & Venue**

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claims occurred in this District.

### **Additional Factual Allegations**

11. A generic drug is a bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Generic drugs are typically sold at substantial discounts from the branded price. According to the

Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies.

12. Antrim is an Illinois-based drug manufacturer, which is primarily in the business of manufacturing and marketing oral liquid and topical liquid pharmaceuticals, including generic drugs.

13. The marketplace for generic drugs is extremely competitive—there are hundreds of generic drug manufacturers competing for FDA approval of bioequivalent drugs.

14. In order to obtain FDA approval for a generic drug, the manufacturer must demonstrate to the FDA that the generic meets the same batch requirements for identity, strength, purity, and quality as the brand-name drug.

15. In light of the relative size of many of the generic drug manufacturers and the equipment cost necessary to develop and manufacture a variety of different product, generic drug companies often outsource the production of their products to contract manufacturers.

16. Bio-Pharm is a contract manufacturer headquartered in Levittown, Pennsylvania. Bio-Pharm markets itself as a specialist in contract manufacturing and Antrim agreed to work with Bio-Pharm as the exclusive manufacturer of the Product.

17. More specifically, the parties agreed as follows:

- a. Bio-Pharm to maintain the confidentiality of all of Antrim's information relating to the Product including, but not limited to, all formulation and testing methodologies, and to manufacture the Product exclusively for Antrim;
- b. Bio-Pharm to prepare regulatory batches of the Product and information relating thereto for Antrim's FDA filing;

- c. Immediately following FDA approval, Bio-Pharm to manufacture and ship the Product consistent with Antrim's ANDA filing, and "good manufacturing practices" as the term is defined by the FDA;
- d. Bio-Pharm to provide Antrim initially with approximately 3300 bottles of the Product for immediate sale following FDA approval, and thereafter with Antrim's "requirements" of the Product as set forth in Antrim's six month forecast;
- e. Following approval and marketing, Antrim to reimburse Bio-Pharm for out-of-pocket costs for its FDA work and FDA batches of the Product – then estimated to be \$125,000, together with the cost of a validation batch;
- f. Following approval and marketing, Antrim to reimburse Bio-Pharm all actual costs of manufacturing the Product batches for sale; and
- g. Bio Pharm to receive 20% of Net Profits for the "life of the Product" (ten years), with "Net Profits" defined as such profits remaining, after deducting the cost of manufacture, taxes, sales and marketing, administration, and costs incurred in connection with the filing and submission of the Escitalopram Oral Solution ANDA for FDA approval.

18. In reliance on this agreement as set forth in various correspondence and communications between the parties, Antrim, with Bio-Pharm's approval and in reliance on Bio-Pharm's promises, listed Bio-Pharm as the sole manufacturer of the Product in its approved ANDA with the FDA. As such, Antrim cannot purchase Escitalopram Oral Solution from another contract manufacturer without FDA approval for a "site change" – a process that takes at least one year.

19. Notwithstanding that agreement between the parties and without due cause, Bio-Pharm has withheld shipment of produced Product in an apparent attempt to coerce Antrim into providing payments in excess of the agreed to amounts.

20. In a recent effort at compromise following wrongful holding of the Product hostage by Bio-Pharm, Antrim agreed to increase Bio-Pharm's interest in the net profits of the Product by 5% to 25% as well as to increase the amount of reimbursement that Bio-Pharm will receive for its costs associated with the FDA application to \$152,000. But despite Antrim's continued good faith attempt at compromise, Bio-Pharm wrongfully breached its agreement, has refused to ship the Product, and Antrim's compromise offer to Bio-Pharm has now lapsed given the time, money and losses suffered by Antrim as a result of Bio-Pharm's breach.

21. In fact and on information and belief, Bio-Pharm may be unlawfully planning to or has shipped batches of the Product already manufactured to a third-party in violation of FDA rules and regulations. Thus, discovery is necessary to obtain a full and complete understanding of the full extent of Bio-Pharm's wrongful conduct.

**COUNT I**  
**BREACH OF CONTRACT**

22. Antrim repeats and re-alleges the allegations set forth in Paragraphs 1 through 21 of this Complaint.

23. The contract between Antrim and Bio-Pharm is valid and enforceable.

24. Antrim has fully performed its obligations under the terms of the parties' agreement, except in cases where Antrim's performance has been excused by Bio-Pharm's breach.

25. Bio-Pharm has breached its agreement by failing to deliver to Antrim the Product for sales and marketing.

**WHEREFORE**, Plaintiff, ANTRIM PHARMACEUTICALS LLC, requests this Honorable Court for the relief specifically detailed below.

**COUNT II**  
**CONVERSION**

26. Antrim repeats and re-alleges the allegations set forth in Paragraphs 1 through 25 of this Complaint.

27. Notwithstanding the agreement between the parties and without due cause, Bio-Pharm has withheld shipment of produced Product in an apparent attempt to coerce Antrim into providing payments in excess of the agreed to amounts.

28. Antrim is the owner of the produced Product that Bio-Pharm is wrongfully withholding.

29. Antrim has a right to immediate possession of the Product.

30. Bio-Pharm has exercised unauthorized control over the produced Product which has interfered with Antrim's ability to sell the Product.

31. Bio-Pharm has continued its wrongful withholding of the produced Product despite multiple demands from Antrim to return it.

**WHEREFORE**, Plaintiff, ANTRIM PHARMACEUTICALS LLC, requests this Honorable Court for the relief specifically detailed below.

**COUNT III**  
**UNJUST ENRICHMENT**

32. Antrim repeats and re-alleges the allegations set forth in Paragraphs 1 through 31 of this Complaint.

33. Without due cause, Bio-Pharm has withheld shipment of produced Product in an apparent attempt to coerce Antrim into providing payments in excess of the agreed to amounts.

34. Antrim is the owner of the produced Product that Bio-Pharm is wrongfully withholding.

35. Bio-Pharm has wrongfully retained the produced Product – a monetarily valuable asset – to Bio-Pharm’s benefit and to Antrim’s detriment and has materially interfered with Antrim’s ability to sell the Product.

**WHEREFORE**, Plaintiff, ANTRIM PHARMACEUTICALS LLC, requests this Honorable Court for the relief specifically detailed below.

**Prayer for Relief**

**WHEREFORE**, Plaintiff, ANTRIM PHARMACEUTICALS LLC requests this Honorable Court for the following relief:

- A. That Bio-Pharm be ordered to pay Antrim all damages flowing from the breach including lost sales and profits on the Product;
- B. That Bio-Pharm be ordered to pay Antrim consequential damages in an amount in excess of \$75,000 exclusive of interests and costs;
- C. That Bio-Pharm immediately return all completed batches of Product to Antrim;
- D. Declaring such agreement terminated;
- E. That Bio-Pharm be ordered to pay Antrim’s attorney’s fees and costs;
- F. For such other and further relief as this Court deems equitable and just.

**Jury Demand**

Plaintiff ANTRIM PHARMACEUTICALS LLC demands a trial by jury on all issues so triable.

Dated: January 19, 2016

Respectfully Submitted,

ANTRIM PHARMACEUTICALS LLC

By: /s/ W. Gordon Dobie  
*One of its Attorneys*

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